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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,668	10/14/2003	Steve Mitchell	KLYCD-05008US1	3396

7590 04/17/2006

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/684,668

Applicant(s)

MITCHELL, STEVE

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-16,18,19,21,23 and 26-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41-43 is/are allowed.
- 6) ☒ Claim(s) 1-6,9-16,18,19,21,23,26-40 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's response filed 3/31/06 has been fully considered.

Regarding the rejection of claim 23 under 35 U.S.C. 112, second paragraph, applicant's arguments are not persuasive. The concave socket in the lower implant is parallel to the sagittal plane as shown in figure 1G. Note that figure 1E does not show the lower implant.

The amendment to claim 1 overcame the rejection in view of Yarrow (4,499,613).

Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Ferree (2004/0106998), applicant's has submitted a declaration to overcome the rejection. However, said declaration is ineffective as detailed in the ***Response to Amendment*** section below.

Regarding the rejection under 35 U.S.C. 102(e) as being anticipated by Wagner et al (6,706,070), the Examiner places strong emphasis on the embodiment shown in figure 42. The Examiner appreciates that applicant's device allows for continuous articulation of adjacent vertebrae allowing for natural bending movement of said vertebrae unlike the embodiments of Wagner et al. However, applicant has not correctly claimed this. The functional language fails to overcome the rejection. The implant of Wanger et al "does not fuse", and is fully capable of readjustment. For example, the device of Wagner is fully capable of the first piece pivoting about the crossbar member to accommodate lateral bending when the surgeon adjusts the implant during the implantation procedure. Regarding the language of at least claim 35, "wherein the

rotation about the first axis is not limited to rotation in only one plane", the device of Wagner fully capable of fulfilling through adjustment of elements 740 and 760.

Response to Amendment

The declaration filed on 3/31/06 under 37 CFR 1.131 has been considered but is ineffective to overcome the undisclosed reference.

The evidence submitted is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the unstated reference (the reference and date should be on the declaration). For an actual reduction to practice, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development; the exhibits do not prove the device was built and tested; "a machine is reduced to practice when it is assembled, adjusted and used." Steve Mitchell stating that "I recall designing" and "I recall attending" is not evidence of an actual reduction to practice. Please describe what claim limitations are being shown in each photo and what claim limitations are not being shown.

The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the unstated reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be

comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). Steven Mitchell recalling designing a prototype is demonstrative evidence.

Pertinent Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Baumgartner et al 2006/0036326 – universal spinal joint.

Eisermann et al 2003/0204261 – universal spinal joint.

Allowable Subject Matter

Claims 41-43 are allowed.

Claim Rejections - 35 USC § 112, Second Paragraph

Claims 21 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 21, “first piece and second piece” lacks antecedent basis.

Regarding claim 23, the claimed configuration is ambiguous. The socket of the lower plate is parallel to the sagittal as shown in figure 1G not perpendicular.

Claim 44 incorrectly defines the socket in the upper implant being parallel to the sagittal plane. This claim directly conflicts with claim 43.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 23, the socket of the lower plate is parallel to the sagittal as shown in figure 1G not perpendicular.

Claim 44 incorrectly defines the socket in the upper implant being parallel to the sagittal plane.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4-6, 9-12, 14, 21, 23, 35-40, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Ferree (2004/0106998).

Note that the provisional application No. 60/416,181 was filed on October 4, 2002 and supports figures 1-6 only. Ferree teaches an implant comprising a first piece 104 having a first socket a second piece 104' having a second socket and a crossbar member 102 that is at least partially received in the first socket and the second socket.

The crossbar member includes first and second bars configured perpendicular forming a "T" or "+" shape.

Regarding claim 5, the socket or interior surfaces comprise many different slopes.

Regarding claim 44, see figure 2, showing the upper implant (second piece) has the socket which is parallel to the sagittal plane of the patient.

Claims 1-6, 9-16, 18-19, 21, 23, 26-40, 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (6,706,070).

Applicant must consider all configurations taught by Wager, a couple configurations are specifically discussed. Referring to figures 8-9, Wagner et al teaches an implant comprising a first piece 12 having a first socket 60, a second piece 14 having a second socket 60 and a crossbar member 30 that is at least partially received in the first socket and the second socket.

Regarding claim 2 having first and second bars that are perpendicular, see figure 6B showing element 30 having generally "I" shape having upper and lower bars separated by a middle bar. **Also see figures 42-49 wherein the spacer (crossbar) includes at least elements 740, 760 and the cam block. All other elements are self-evident. See the embodiments shown in figure 38 wherein the bars abut.**

Claims 3 and 26, inherently the "I" shape has a bar above the middle bar. Also, referring to figure 9, another interpretation the first bar 30 is mounted higher or above second bar 32.

Regarding claim 12, see at least figure 42.

Regarding at least claims 15-20 claiming a keel, see at least elements 516, 616, 716, 816, 916, 1016.

Regarding claim 44, see at least figure 42, showing the upper implant (second piece) has the socket which is parallel to the sagittal plane of the patient.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferree (2004/0106998) in view of Marnay (WO 01/01893).

Ferree teaches the implant as described above, however, fails to teach a keel. Marnay teaches the keel configuration as claimed. It would have been obvious to one having ordinary skill in the to have used the keel/s of Marnay on the implant of Ferree to better anchor it to the vertebrae.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

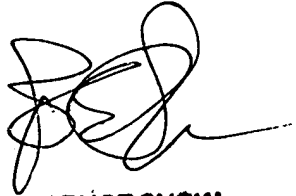
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes



BRUCE SNOW
PRIMARY EXAMINER